NDA 18-604/S-016
NDA 18-604/S-018

GlaxoSmithKline
Attention: Beth Austin, Ph.D.
Project Director, Regulatory Affairs
Five Moore Drive
Research Triangle Park, NC 27709

Dear Dr. Austin:

Please refer to your supplemental new drug applications dated June 8, 1999 and August 24, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Zovirax™ (acyclovir) Ointment.

We acknowledge receipt of your submissions dated:

November 5, 1999
November 2, 2000
November 29, 2000
March 21, 2001 (2)
April 6, 2001 (2)

These supplemental new drug applications provide for updating the package insert for the ointment to reflect changes made to the oral and intravenous product labeling and to comply with the provisions of the Geriatric labeling requirements promulgated on August 27, 1999 under 21 CFR 201.57(f)(10).

We have completed the review of these supplemental applications, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text. Accordingly, these supplemental applications are approved effective on the date of this letter with the following minor revision, as discussed with Dr. Austin on May 7, 2001:

In the VIROLOGY section, under Drug Resistance, the first sentence will read:

> "Resistance of HSV and VZV to acyclovir can result from qualitative and quantitative changes in the viral TK and/or DNA polymerase."

The final printed labeling (FPL) must be identical to the submitted draft labeling dated April 10, 2001 and must include the revision stated above. Please submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavyweight paper or similar material. Alternatively, you may submit the FPL electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDAs* (January 1999). For administrative purposes, this submission should be designated "FPL for approved supplement NDA 18-604/S-16 and S-018." In addition, please provide a clean text MS Word version of the label as a desk copy.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Practitioner" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please call Karen A. Young, RN, BSN, Regulatory Project Manager, at (301) 827-2335.

Sincerely,

Debra B. Birnkrant, M.D.
Acting Director
Division of Antiviral Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research